# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NEAL ROSEN, SCOTT D. KUDUK, SAMUEL J. DANISHEFSKY, FURZHONG F. ZHENG, LAURA SEPP-LORENZINO, and OUATEK OUERFELLI

Appeal No. 2006-1468
Application No. 09/937,192

HEARD: JULY 11, 2006



Before ADAMS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 4, 6 and 9-34. Claims 3, 12 and 13 are representative of the claims on appeal, and read as follows:

3. A chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.

12. A method for destruction of cells expressing a HER-family tyrosine kinase, comprising administering to the cells a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.

13. A method for treating cancer in a patient suffering from cancer, comprising administering to the patient a therapeutic composition comprising a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second hsp-binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90.

Claims 12-30 and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not enable the full scope of the claimed subject matter. In addition, claims 3, 4, 6 and 9-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Finally, 3, 4, 6 and 9-34 stand provisionally rejected under the judicially created doctrine of obviousness-type patenting as being unpatentable over claims 1, 2, 6, 7, 12, 13 and 15-40 of copending application 09/960,665. As appellants do not argue the merits of the provisional obviousness-type double patenting rejection, we summarily affirm that rejection. After careful review of the record and consideration of the rejections under 35 U.S.C. § 112, first and second paragraphs, we reverse.

## DISCUSSION

Claims 12-30 and 32-34 stand rejected under 35 U.S.C. § 112, first paragraph,

> because the specification, while being enabling as a method of treating HER-2 expressing cancer using geldanamycin dimer linked by a 4-carbon chain at the 17-positions of each, does not reasonably provide enablement for treating any and all cancers and for destruction of other cells or treating cancers generally using "a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 with which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker, wherein the first and second binding moieties are each an ansamycin antibiotic and retain the ability in the chemical compound to bind to the pocket of hsp90."

Examiner's Answer, page 3.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided

"acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

While the examiner engages in a Wands analysis, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988) (noting that facts that should be considered in determining whether a specification is enabling include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims), the examiner's primary concern appears to be that "[t]here is no general treatment for cancer and there is no correlation between the assays relied upon by applicants and the ability to treat all cancers." Examiner's Answer, page 4. The examiner states:

> The claims are drawn to disorders that are not related and whose treatment using a single compound is unknown. Pancreatic cancer, for example, has proven extremely difficult to treat. Gastric cancer embraces several different types of cancers which includes, Adenocarcinomas (cancers started in the gland cells in the stomach lining), Squamous cells cancers are cancers in the skin-like cells that are mixed with gland cells to make the stomach lining, Lymphomas, sarcomas (cancer that begins in the muscle layer of the stomach is sarcoma) and Neuroendocrine tumours (cancers that grow in hormone producing tissues, usually in the digestive system). Treatment for each is different.

Id. at 6. The examiner, however, provides no evidence to support the above.[1]

The examiner also asserts that there is no predictability because the invention is pharmaceutical in nature, and that "the amount of guidance presented in the specification as to which compounds are sufficiently active to be useful for the claimed uses is nonexistent." Id. at 5. Again, the examiner has provided no evidence or scientific reasoning to support those assertions, and thus has not met his burden in demonstrating that the specification fails to enable the full scope of the claimed subject matter. In addition, the treatment of "any and all cancers" is not the proper standard as a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), In re Cook, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971).

Moreover, appellants have provided evidence demonstrating that a monomeric ansamycin compound, as well as other hsp90 inhibitors "are efficacious in a variety of tumor types including breast cancer, ovarian cancer, pancreatic cancer and gastric cancer . . ., other HER kinase overexpressing tumors, and tumors which do not over express HER kinase." See Appeal Brief,

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[1] The examiner does cite Sreedhar et al., Biochimica et Biophysica Acta, pp. 233-242 (2004). Appellants state in the Reply Brief that the Sreedhar reference is not of record, and we also could not find it in our review of the record. In response, the examiner merely stated that "[t]he reply brief . . . has been entered and considered." Paper mailed February 17, 2006. Thus, we have not considered the examiner's arguments to the extent that they rely upon the Sreedhar reference.

page 9, as well as the references cited by Appellants on that page. Again, the examiner has not brought in any evidence or provided any scientific reasoning to refute the evidence provided by appellants.

Therefore, as the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first paragraph, we are compelled to reverse the rejection.

Claims 3, 4, 6 and 9-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that appellant regards as the invention. See examiner's Answer, page 7.[2]

The examiner's first concern is that "[t]he metes and bounds of . . . 'ansamycin' are unknown." As noted by appellants, however, "[t]he term 'ansamycin antibiotic' is a recognized term of art," see Appeal Brief, page 12,[3] and the examiner has provided no evidence to demonstrate that there is confusion in the art regarding that term.

The examiner's second concern is that the nature of the linker is unknown. See Examiner's Answer, page 7. As noted by appellants, see Appeal Brief, page 14, the specification at page 4 and page 6, describe the linker, and how activity varies with linker length. Thus, we find that one skilled in the art

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[2] The examiner designates this rejection as a "New Grounds of Rejection." See Examiner's Answer, page 7. As noted by appellants, however, see Reply Brief, page 1, the rejection appeared in the non-final rejection mailed July 11, 2005.

[3] See also Rinehart, "Antibiotics with Ansa Rings," Accounts of Chemical Research, Vol. 5, pp. 57-64 (1972), attached to the Appeal Brief, which discusses the then new class of ansamycin antibiotics.

would understand the metes and bonds of the term linker. See Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987) (noting that claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits.").

The examiner's third concern is with the term bind. According to the examiner, "[t]he term 'bind' in the claims is indefinite There is no way of knowing whether a given compound would bind. Binding is a process which cannot be observed, merely inferred, which is unreliable." Examiner's Answer, page 8. We cannot understand the examiner's concern in this regard, however, because "bind" is an art recognized term, and it is unclear if "bind" is unacceptable, what term would be acceptable to the examiner.

Finally, the examiner objects to the term "retain the ability to bind," asserting that it is unclear. According to the examiner:

> Does it mean that the compound is supposed to bind exactly as strongly as the monomer binds or does it mean that it simply needs to bind? Both definitions could be valid, but Appellants need to clarify whether the term "retain" means as strongly or weakly as the monomer or simply the ability with no regard as to how it accomplishes the binding.

Id.

From the examiner's statement that "[b]oth definitions" he proposes are valid, the examiner understands what is meant by the phrase "retain the ability to bind." The examiner's concern thus appears to be the breadth, however, "breadth is not to be equated with indefiniteness." In re Miller, 441 F.2d 689,

693, 169 USPQ 597, 600 (CCPA 1971); see also In re Hyatt, 708 F.2d 712, 714-15, 218 USPQ 195, 197 (Fed. Cir. 1983).

For the reasons set forth above, the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, second paragraph, is reversed.

## CONCLUSION

Because the examiner has failed to set forth a prima facie case of unpatentability under 35 U.S.C. § 112, first or second paragraph, the rejections under those sections of the statute are reversed. Because appellants do not argue the merits of the provisional obviousness-type double patenting rejection, we summarily affirm that rejection.

## AFFIRMED

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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